HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

92080d

Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

# *WARNING LETTER*

Cin WL – 11877-02
December 20, 2001

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

Mr. John Harryman.
Chief Executive Officer
Norton Suburban Hospital
4001 Dutchmans Lane
St. Matthews, KY 40207

Facility I.D.#: 140996

Dear Mr. Harryman:

A representative from the Commonwealth of Kentucky acting on behalf of the Food and Drug Administration (FDA) inspected your facility on December 13, 2001. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

**Quality Assurance – Equipment - 21 CFR 900.12(e)(2)**

Your records revealed that your facility phantom quality control records for the mammography units in rooms 1 and 2 were missing for at least four weeks. The MQSA regulation requires each mammography unit be evaluated by performing at least weekly the image quality evaluation test.

The inspection found that your facility failed to perform this weekly quality control test during the seven consecutive weeks of January 8 through February 24, 2001. This noncompliance issue was also observed for the weeks of March 12-17, 2001 and October 15-20, 2001.

Because this condition may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, this represents violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

The other item listed in the December 13, 2001 inspection report identified, as Level 3 should also be corrected. We will verify correction of this item during our next inspection. You are not required to address the Level 3 item in your written response.

You must act on these matters immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violation noted in this letter; and
- Each step your facility is taking **to prevent the recurrence of similar violation.**

Please submit sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

Also, please **send a copy** to the State radiation control office:

Ms. Julie Keightley
Commonwealth of Kentucky
Radiation Health & Toxic Agents Branch
3810 Glenwillow Way
Louisville, KY 40299

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,

Henry L. Fielden
District Director
Cincinnati District Office